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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

CHURCH & DWIGHT CO., INC.,

Plaintiff,

v.

SPD SWISS PRECISION DIAGNOSTICS, GMBH,

Defendant.

Civil Action No. 14 CV 585 (AJN)

MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANT'S MOTION *IN LIMINE* TO DISMISS ALL FALSE ADVERTISING CLAIMS

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES

Statutes

Other Authorities

INTRODUCTION

In the first paragraph of its Motion In Limine brief ("SPD Br.") (Dkt. 224), Defendant SPD informs the Court of two alleged facts it says require the dismissal of Plaintiff C&D's Lanham Act claim. First, SPD alleges that C&D's claim "challenges advertising that was expressly approved – indeed mandated by" FDA. Second, SPD alleges that C&D "seeks to overturn the FDA's clearance of" SPD's Weeks Estimator home pregnancy test (the "Weeks Estimator" or "Product"). *Id.* at 1.

Both alleged facts are untrue. Addressing the latter allegation first, C&D **does not** seek to overturn FDA's clearance of the Product for the intended use of (i) detecting whether or not a woman is pregnant and (ii) estimating how many weeks since she last **ovulated**. C&D does not object to the Product being marketed for that intended use.

C&D **does** object to SPD's campaign of falsely advertising that the Product estimates how many weeks a woman is **pregnant**. But FDA **never** cleared the Product for that intended use, and therefore, SPD's contention that C&D is asking this Court to overturn FDA's clearance is false. In arguing otherwise, SPD mischaracterizes the testimony of certain C&D witnesses, but it would not matter even if SPD described that testimony correctly. It is C&D's Complaint that frames the relief it seeks from this Court, not the isolated snippets of testimony SPD claims to have elicited from a particular witness. The Complaint, as well as the references to it by C&D's counsel, make clear that the only relief sought concerns SPD's false advertising of the Product for purposes for which the Product was never cleared by FDA. *See* Point VI, *infra*.

The other factual premise on which SPD bases its motion is likewise untrue. There are, as this Court knows, numerous Weeks Estimator advertisements C&D claims to be false or misleading. They include SPD's nationally aired television commercial (the "Commercial"); the first Weeks Estimator package in which SPD sold the Product (the "Original Package");

statements on SPD's website; point-of-purchase advertisements; a press release, and advertisements to retailers. *See* Opinion and Order Denying SPD's Motion to Dismiss (Dkt. 93) ("MTD Op.") 3-5. None of these advertisements was ever "approved" by FDA, much less mandated. SPD disseminated those advertisements without FDA pre-clearance and when FDA ultimately saw the Commercial and Original Package, it directed SPD to stop airing the Commercial and stop selling the Original Package, after which SPD also stopped or modified other challenged advertisements.

Contrary to SPD's contention, FDA did not "mandate" a single one of the challenged advertisements. Indeed, the only ones it appears to have "permitted" are SPD's revised Weeks Estimator package (the "Revised Package") and a modified version of the Commercial, which FDA allowed SPD to broadcast in that form only on the internet (the "Internet Commercial"). SPD's brief goes on at length about FDA's involvement in reviewing those two advertisements and an early version of the Weeks Estimator package that SPD never used. But as we will show, SPD's description of FDA's role is both factually inaccurate and legally irrelevant.

The Supreme Court's unanimous opinion in *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228 (2014), decided shortly after this Court's MTD Opinion, fully disposes of SPD's argument that FDA's acceptance of the Revised Package and Internet Commercial, or of the early, never-marketed version of the Weeks Estimator package, immunizes SPD from Lanham Act liability. Simply stated, *POM Wonderful* holds that the Federal Food, Drug, and Cosmetic Act ("FDCA") does not preclude Lanham Act false advertising claims **even when FDA permitted or required the challenged advertising**. *See* Point II, *infra*. Although *POM Wonderful* involved FDA juice beverage regulation, its holding applies here as well – a point made clear not only by the Supreme Court's statutory analysis and rationale for its decision, but

also by this Court's recognition that the FDA Clearance Letter expressly cautions that it should not be viewed as a determination that the Weeks Estimator's labeling complies either with the FDCA or any other federal statute, and by the two post-*POM Wonderful* federal court decisions that have recognized that *POM Wonderful* applies to medical device regulation.

Indeed, it is a measure of SPD's overreach that it now claims the Supreme Court decision supports its position after SPD heavily relied in its unsuccessful motion to dismiss on the very appellate decision the Supreme Court reversed. But nimble footwork cannot obscure the principle that guided the Supreme Court's opinion: a competitor receives no license to violate the Lanham Act simply because some of its advertising may have been permitted – or even "mandated" – by FDA.

THE RELEVANT FACTS

C&D's Complaint

Just as in its motion to dismiss, SPD's Motion In Limine materially mischaracterizes the Complaint. SPD asserts that the Complaint "challenged the advertising for the Weeks Estimator as unlawful **because** the advertising allegedly violated marketing restrictions imposed by the FDA." SPD Br. 2.[1] That is not correct, as this Court has already found.

C&D's Lanham Act claim does not depend on the fact that SPD's advertising violated FDA labeling restrictions. Instead, C&D claims that SPD is liable under the Lanham Act because SPD's advertising falsely communicates that the Weeks Estimator can estimate how many weeks a woman is pregnant when, in fact, the Product cannot do so, and that SPD's advertising misleads consumers in ways that, among other things, caused commercial injury to C&D. Thus, C&D seeks to hold SPD liable for the competitive injury SPD caused it to incur by

[1] In this brief, all emphasis in quotations is added unless otherwise indicated.

spreading these falsehoods. This Court agreed with this construction of the Complaint. MTD Op. 17-18.[2]

While the Complaint alleged, and C&D will prove at trial, that FDA *agrees* with C&D's position and that FDA did not clear the Product for the intended use of estimating the number of weeks a woman is pregnant, this does not mean C&D is attempting to privately enforce the FDCA. Instead, C&D is relying on FDA's scientific conclusion about what the Product can and cannot do as additional factual support for its Lanham Act claim. This Court agreed that with regard to C&D's "reference in its Complaint to the FDA's scientific findings, a number of courts have held that courts may consider the FDA's positions on a matter as evidence of falsity in considering a Lanham Act claim." MTD Op. 19.

FDA's Clearance of the Weeks Estimator

SPD also misrepresents the facts pertaining to FDA's clearance. SPD contends that correspondence between it and FDA shows that FDA had "full control" over "every element" of the Weeks Estimator package. SPD Br. 17, 20. But far from that, during the clearance process FDA confined its commentary to specific elements of the packaging and package insert, and permitted SPD to use its own language and graphic elements so long as they did not encroach on FDA's user safety concerns. For example, in a "Hold Letter" FDA sent in September 2012 identifying labeling changes it wished SPD to make, FDA told SPD that a particular statement "***may be*** included" in the package insert, but did not say it must be included. Ex. 1 at 6.[3] Rather than believing it was restricted from making further package label changes without FDA

[2] On this issue, nothing has changed since the date of the MTD Opinion. The position the Court correctly attributed to C&D about the meaning of the Complaint remains C&D's position.
[3] Citations to "Ex." refer to exhibits to the February 17, 2015 Declaration of Baldassare Vinti ("Vinti Decl."). Our citations to exhibits with ECF-stamped page numbers, such as the Hold Letter, refer to the exhibit's ECF-stamped page numbers. Our citations to Bates-stamped exhibits refer to the last three numbers of the exhibit's Bates-stamped page numbers.

approval, [redacted] Ex. 2 at 204. Thus, it simply was not the case that FDA exercised total control over all elements of the Weeks Estimator package it cleared (which in any event was a **different** package than the one SPD **unilaterally** decided to use without informing FDA). *See* pp. 8-9, *infra*.

The Motion In Limine is based in large part on SPD's characterization of one aspect of the Hold Letter: a direction by FDA for SPD to remove a "statement describing the minimum accuracy of the weeks estimation indicator." Ex. 1 at 6. We show in Point IV that (i) SPD has mischaracterized the Hold Letter on this point, and (ii) even if SPD's characterization of the Hold Letter were completely accurate, its motion still must fail.

FDA's Supposed "Express Approval" of the Challenged "Advertising"

As noted, SPD alleges that FDA "expressly approved – indeed mandated" the "advertising" C&D challenges in this case. SPD Br. 1. That is false. By use of the umbrella term "advertising," SPD conflates all of the various Weeks Estimator advertisements at issue. In fact, FDA did not "mandate" any of the challenged advertisements, and with the lone exceptions of the Revised Package and Internet Commercial, it did not even review, much less approve, any other advertisement at issue.

First, SPD does not dispute that FDA **never saw** the Original Package in which SPD first sold the Weeks Estimator until months after SPD began selling the Product in that Package. *See* SPD Br. 9-10. That is because, before FDA issued its Clearance Letter, SPD misrepresented to FDA that a different version of the Weeks Estimator Package was the "final" package. Ex. 3 ¶¶ 34-41; Ex. 4 at 1; Ex. 5 at 32. [redacted] Ex. 6 at 176:11-177:12, 187:10-192:5. Although approximately **eight months** elapsed from the time of

the FDA Clearance Letter (December 2012) until SPD first sold the Product in the Original Package (August 2013), SPD never alerted FDA to the changes from the version FDA had cleared, nor did SPD submit the Original Package to FDA for review and clearance. Ex. 3 ¶ 41.

Unable to deny that FDA never reviewed or cleared the Original Package, SPD alleges that FDA's clearance of the previous, supposedly "final" package is tantamount to clearance of the Original Package because the two packages are identical apart from two supposedly "minor deviations." SPD Br. 14, 21. But FDA certainly did not view those deviations as "minor."[4] Instead, when FDA eventually saw the Original Package, it found that it violated the Clearance Letter (Exs. 9 & 11), [redacted] (Ex. 10 at 022), and told SPD to stop using the Original Package. In short, FDA never cleared the Original Package; rather, it cleared what it found to be a "very different" package.

SPD goes to the extreme of asserting that in clearing the Product for sale in the supposedly "final" package that SPD did not use, SPD's clearance "necessarily mean[s] that FDA concluded that these marketing requirements were sufficient to prevent consumers from being confused and thereby harmed" within the meaning of the FDCA. SPD Br. 14. But SPD's assertion is directly contradicted by the text of the Clearance Letter which (as this Court recognized, MTD Op. 8) explicitly states that FDA's clearance "**does not mean that FDA has** made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies." Ex. 31 at 3. In short, as the Clearance Letter makes clear, FDA's clearance was not a finding by FDA that the Product labeling complied with the FDCA, the Lanham Act, or any other Federal statute.

[4] The supposedly "final package" that FDA cleared is Ex. 7; the Original Package in which SPD first marketed the Product is Ex. 8.

Nor did FDA approve the original television Commercial. To the contrary, it is undisputed that FDA never saw the Commercial until after SPD began airing it. SPD suggests that because FDA later reviewed and acquiesced to the internet-only dissemination of the Internet Commercial, this qualifies as an implicit FDA blessing of the original Commercial, which SPD mischaracterizes as "substantially similar." SPD Br. 10. That contention is absurd.

Far from blessing the Commercial, FDA explicitly directed SPD to take it off the air. *See* Ex. 11 at 5. FDA did so because it was concerned the Commercial "conveys the message that the Weeks Estimator can be used for measuring the number of weeks of pregnancy" and therefore "may be misleading to a consumer." Ex. 12 at 3. Indeed, FDA was so concerned the Commercial was misleading that FDA rejected SPD's request to allow it to continue airing the Commercial for another 10 days, and instead directed SPD to stop broadcasting it sooner. Ex. 11 at 5. To portray that as an endorsement of the Commercial or its message is frivolous.

Needless to say, that obvious fact is not changed by FDA's eventual, limited acquiescence to the very different Internet Commercial. Unlike the original Commercial, the pregnant woman character in the Internet Commercial does not say aloud that she is two weeks pregnant. Instead, she merely holds up a test stick that reads "Pregnant 1-2." *See* Ex. 13 ¶¶ 32-34, 38; Exs. 14-17. Also, when the test stick is shown in the original Commercial it reads "Pregnant 1-2 ***weeks***"; the word "weeks" was removed in the Internet Commercial. *Id.* The original Commercial also heightened the false communication that the Weeks Estimator provides the same estimate as a doctor via the pregnant woman's specific statement that she knows she is two weeks pregnant even though she has not yet seen her doctor. *Id.* This reference was removed in the Internet Commercial. *Id.* In addition, the indication for use statement (which, among other things, says that the Product ***does not*** provide the same estimate as a doctor) is

shown for an extended period on a full screen in the Internet Commercial whereas, in the original Commercial, only parts of it were displayed very briefly and then only at the bottom of the screen in 'mice type' font. *Id.*[5]

There is also no evidence that FDA ever reviewed, let alone cleared, the other advertising C&D challenges. *See* MTD Op. 3-5, 24 n.7. Thus, the only advertisement FDA actually reviewed and permitted other than the Internet Commercial was the Revised Package. But contrary to SPD's assertion that FDA "mandated" either the Original or Revised Package, both the 510k clearance process and the subsequent process that led to FDA's acceptance of the Revised Package in place of the Original Package actually involved SPD making proposals to FDA and then FDA either accepting or rejecting those proposals.

For example, SPD initially proposed to call the Product the "Conception Indicator," but FDA rejected that name, leading SPD to suggest "Weeks Indicator." *See* Ex. 18 at 193; Ex. 19 at 240. FDA told SPD to change the name to "Weeks Estimation Indicator" to avoid suggesting that the Product's result is definitive. Ex. 1 at 6; Ex. 20 at 677. SPD suggested the less cumbersome name "Weeks Estimator," which FDA agreed to. Ex. 20 at 677. FDA ***did not prevent SPD from suggesting other names***, such as "Weeks Since Ovulation Estimator" (which actually describes what the Product purports to do, but which SPD knew would have little, if any, commercial appeal). Similarly, as to both the supposedly "final" package SPD submitted to FDA but never used, and the Revised Package, it was SPD, not FDA, that designed the package; SPD then requested FDA to confirm that its proposed design was acceptable, and SPD refined the design based on FDA's feedback regarding specific elements. *See, e.g.*, Ex. 19 at 351-53;

[5] To be clear, it is C&D's position that the Internet Commercial, although very different from the original Commercial, is still deceptive.

Ex. 1; Ex. 11 at 3-4. (As noted, in the case of the Original Package, SPD then made additional changes it did not clear with FDA). *See* pp. 5-6, *supra*.

SPD followed the same process for the Internet Commercial. Ex. 11 at 4-5. In short, SPD created all the false advertising that C&D challenges and, while SPD modified the labeling to reflect some of FDA's views, there is no evidence whatsoever FDA would have forbidden SPD from making other changes to the labels to eliminate the false and misleading messages the evidence at trial will prove they convey.

ARGUMENT

I. THE PURPOSE OF FDA'S REGULATION OF THE WEEKS ESTIMATOR PACKAGES WAS TO PROTECT THE HEALTH AND SAFETY OF WOMEN WHO USE THE PRODUCT, NOT TO PROTECT SPD'S COMPETITORS FROM INJURY CAUSED BY SPD'S FALSE ADVERTISING

In its MTD Opinion, this Court recognized that FDA regulates Class II medical devices, including the Weeks Estimator, for a purpose other than protecting the manufacturer's competitors from commercial injury caused by the manufacturer's false advertising. As will appear below, that fact is crucial to the outcome of SPD's motion.

FDA regulates Class II devices such as home pregnancy tests under the Medical Devices Amendments Act ("MDAA") provisions of the FDCA. MTD Op. 6. Under the provisions of 21 U.S.C. § 360(k), colloquially referred to as the "510(k) process," a party seeking to market a new home pregnancy test for a particular intended use must first obtain clearance from FDA. FDA clearance of home pregnancy tests entails, *inter alia*, FDA's review of product packaging. MTD Op. 6-8, 15-16. When (as with the Weeks Estimator) FDA concludes there is a reasonable likelihood a device would be "used for an intended use not identified in the proposed labeling," FDA, through "special controls" procedures, can impose limitations on how the device is marketed. *Id*. 6-8, 16.

Although there is a level of direct FDA involvement in the 510(k) clearance process, FDA regulation of Class II devices, even those subject to special controls, is less stringent than with Class III devices, which are subject to a highly detailed premarket approval process not required of Class II devices. MTD Op. 6-7. Regulation of Class III devices is, in turn, much less rigorous than for prescription drugs. *See generally* 21 U.S.C. § 355; *see also* Note: *What is "Experimental Medical Treatment"?: A Legislative Definition is Needed*, 44 Clev. St. L. Rev. 67, 70 (1996) ("Different medical technologies go through different regulatory processes: prescription drugs go through a rigorous regulatory process, 'medical devices go through a less rigorous process, ...'").

This Court recognized that the purpose of FDA regulation of home pregnancy tests is not to protect competitors' commercial interests (which is what Congress intended the Lanham Act to accomplish), but "instead [is] directed to ensuring that . . . medical devices are safe, effective and not misbranded." MTD Op. 13. This Court (correctly anticipating the Supreme Court's *POM Wonderful* decision) also recognized that in deciding the FDA preclusion issue presented here, the fact that the Lanham Act and the FDCA's medical device regulatory provisions have distinctly different purposes is of vital significance. As this Court explained, "[h]ere, the differing purposes of the FDCA and Lanham Act are thrown into stark contrast: from the perspective of the FDA, so long as the consumer is adequately informed about the use of the Weeks Estimator post purchase and does not misunderstand its results, the FDA's safety concerns are addressed. But from the perspective of a competitor concerned about the consumer's purchasing decision, at that [post purchase] stage the harm that the Lanham Act seeks to prevent will already have been accomplished if the consumer was misled into purchasing the Weeks Estimator with a mistaken belief as to its function." *Id*. 24 n.6.

The evidence C&D will present at trial will show that precisely the sort of consumer deception at the point of purchase that this Court surmised could happen **did in fact happen** extensively. *See* Point V, *infra*. In sum, if **after buying the Product and before using it**, a consumer takes the time to read the package insert materials and understands from them that the Weeks Estimator's estimate of 'weeks' is weeks since ovulation, not weeks pregnant, and is substantially different than the number of weeks pregnant her doctor will tell her, FDA's goal of preventing Product misuse will be achieved. By contrast, the Lanham Act's purpose of protecting SPD's competitors from harm from false advertising will not be.

II. THE SUPREME COURT'S *POM WONDERFUL* DECISION

In denying SPD's motion to dismiss, this Court stated that "it may be that SPD is able to re-raise [its FDCA preclusion] argument at a later stage, if appropriate given the development of the proceedings." MTD Op. 25. That statement recognized that some of SPD's communications with FDA were not properly part of the record on the motion to dismiss, and also reflected the Court's belief that SPD should be given a chance to show that there "existed an actual conflict between an FDA action or regulation and [C&D's] claims." *Id.* 21. The Court's view that an "actual conflict" might result in partial preclusion of C&D's Lanham Act claim appears to have been based substantially on the Ninth Circuit's *POM Wonderful* opinion, 679 F.3d 1170, 1176-77 (9th Cir. 2012). *See* MTD Op. 21-22 (describing the Ninth Circuit's decision as "holding that plaintiff's claim based on the name and label of the product was barred because FDA regulations authorized the name [defendant] Coca-Cola had chosen, such that 'POM's challenge . . . would create a conflict with FDA regulations and would require us to undermine the FDA's apparent determination that so naming the product is not misleading'").

On June 12, 2014, nine days after this Court's MTD Opinion, the Supreme Court unanimously reversed the Ninth Circuit's *POM Wonderful* decision.[6] In its Motion In Limine brief, SPD cites only a few short snippets from the Supreme Court decision in attempting to justify SPD's contention that *POM Wonderful* "did nothing to erode the 'actual conflict' line of cases" and "Reaffirmed Preclusion of Lanham Act Claims That Directly Conflict With FDA Action." SPD Br. 18. SPD's contention is fundamentally wrong, as we will now show.

As Justice Kennedy's unanimous opinion explained, Coca Cola marketed a Minute Maid brand juice drink that the product label identified as a "pomegranate blueberry flavored blend of 5 juices", with the words "pomegranate blueberry" appearing in all capital letters and in far larger type than the other words about the drink's contents. 134 S. Ct. at 2235. To accentuate the label's focus on pomegranates and blueberries, the label featured a "vignette of blueberries, grapes and raspberries in front of a halved pomegranate and a halved apple." *Id*.

Coca-Cola's product did contain pomegranate juice and blueberry juice, but only in minute quantities. Combined, the product contained 0.5% pomegranate and blueberry juice, compared to over 99% apple and grape juices. *Id*. This infuriated Coca-Cola's competitor POM, whose drinks were laden with pomegranate juice. POM believed the Minute Maid label grossly exaggerated the amount of pomegranate and blueberry juice in the product, and would deceive consumers looking to buy a drink containing substantial amounts of pomegranate juice into buying Minute Maid instead of POM's juice drinks. *Id*. So POM sued Coca-Cola for false advertising under the Lanham Act.

However, in Coca-Cola's view, which the District Court adopted in granting partial summary judgment against POM, POM's Lanham Act claim had a fatal problem, namely that

[6] The decision was 8-0, with Justice Breyer taking no part. 134 S. Ct. at 2232.

FDA closely regulates fruit juice labels through comprehensive, detailed regulations about the contents of those labels. As the Supreme Court explained it, the "District Court reasoned that in the juice blend regulations, the 'FDA has directly spoken on the issues that form the basis of POM's Lanham Act claim against the naming and labeling of' Coca-Cola's product, but has not prohibited any, and indeed expressly has permitted some, aspects of Coca-Cola's label." 134 S. Ct. at 2236, *quoting* 727 F. Supp. 2d 849, 871-73 (C.D. Cal. 2010).

The Ninth Circuit affirmed the District Court's grant of summary judgment in an opinion SPD later relied on heavily in its motion to dismiss. According to the Supreme Court, the Ninth Circuit "reasoned that Congress decided to 'entrust matters of juice beverage labeling to the FDA'; the FDA has promulgated 'comprehensive regulation of that labeling'; and the FDA 'apparently' has not imposed the requirements on Coca-Cola's label that are sought by POM." 134 S. Ct. at 2236, *quoting in part* 679 F.3d at 1178. Thus, under Ninth Circuit precedent, "for a court to act when the FDA has not – despite regulating extensively in this area – would risk undercutting the FDA's expert judgment and authority." 679 F.3d at 1177.

The Supreme Court granted certiorari and unanimously reversed. In doing so, it flatly rejected both the Ninth Circuit's holding that FDA's comprehensive regulation of juice beverage labeling barred POM's Lanham Act suit, and the U.S. Government's narrower position that POM's suit was precluded only "to the extent the FDCA or FDA regulations **specifically require or authorize** the challenged aspects of [the] label." 134 S. Ct. at 2240, *quoting* Brief for United States as *Amicus Curiae* ("Amicus Br.") 11. Because the Supreme Court's rationale for reversal is dispositive of SPD's Motion in Limine, we discuss the Court's analysis in detail.

To begin with, the Supreme Court emphasized that "this is a statutory interpretation case and the Court relies on traditional rules of statutory interpretation." 134 S. Ct. at 2236. The

Court "observed that neither the Lanham Act nor the FDCA, in express terms, forbids or limits Lanham Act claims that are regulated by the FDCA." *Id*. at 2237.

The Supreme Court then characterized the Lanham Act's imposition of liability for false advertising as "comprehensive" and found that it extends to "misrepresentations on labels," including labels of FDA-regulated products. *Id*. The Court observed that "[n]o other provision in the Lanham Act limits that understanding or purports to govern the relevant interaction between the Lanham Act and the FDCA," and that "the FDCA, by its terms, does not preclude Lanham Act suits." *Id*. As a result, the Court concluded that FDA-regulated juice labels "are not, under the terms of either statute, off limits to Lanham Act claims. No textual provision in either statute discloses a purpose to bar unfair competition claims like POM's." *Id.* The above analysis applies with equal force to Class II medical devices, and SPD cites no language in the MDAA or in any FDA regulation concerning Class II devices that so much as mentions the Lanham Act, let alone indicates that FDA review and clearance of Class II device labels immunizes a device manufacturer from Lanham Act liability for false advertising that appears on the label of a cleared device (or elsewhere). Indeed, FDA's Clearance Letter to SPD says precisely the opposite. *See* MTD Op. 8.

The Supreme Court deemed the absence of language in either statute giving precedence to FDA regulation over Lanham Act suits to be "of special significance because the Lanham Act and the FDCA have coexisted since the passage of the Lanham Act in 1946. If Congress had concluded, in light of experience, that Lanham Act suits could interfere with the FDCA, it might well have enacted a provision addressing the issue during these 70 years." 134 S. Ct. at 2237 (citations omitted). The fact that Congress amended both statutes over the years, but "did not enact a provision addressing the preclusion of other federal laws that bear on food and beverage

labeling . . . is 'powerful evidence that Congress did not intend FDA oversight to be the exclusive means' of ensuring proper food and beverage labeling." *Id*. (citation omitted). Apart from the fact that the MDAA has been in effect for 39 years, not approximately 70, the above analysis applies with equal force to Class II devices.

The Supreme Court found additional evidence that Congress did not intend the FDCA to preclude Lanham Act suits in the language and content of the FDCA's preemption provision applicable to juice labels. That provision expressly preempted certain **state** laws that imposed requirements "not identical to" the relevant FDCA provisions, but contained no language suggesting any "intent to preclude **federal** claims." *Id*. at 2238. Significantly, the FDCA's medical device preemption provision is materially identical to the juice label provision cited by the Supreme Court. *Compare* 21 U.S.C. §343-1 *with* 21 U.S.C. §360k (Exs. 22 and 23).

Also central to the Supreme Court's decision was its recognition (foreshadowed by this Court nine days earlier, *see* MTD Op. 13, 15, 24 n.6) of the separate purposes Congress intended the Lanham Act and the FDCA to serve. As the Supreme Court noted, the "Lanham Act creates a cause of action for unfair competition through misleading advertising or labeling. Though in the end consumers also benefit from the Act's proper enforcement, the cause of action is for competitors, not consumers." 134 S. Ct. at 2234. Thus, "the Lanham Act's purpose" is to "protect persons engaged in [commerce within the control of Congress] against unfair competition." *Id*. at 2234, *quoting Lexmark Int'l, Inc. v. Static Control Components, Inc*., 134 S. Ct. 1377, 1389 (2014). By contrast, the "FDCA statutory regime is designed primarily to protect the health and safety of the public at large." *Id*. at 2234. In that regard, the purpose of the FDCA statutory regime for juice labels is the same as for Class II devices. *See* MTD Op. 13.

The Supreme Court viewed the FDCA and Lanham Act as "complement[ing] each other" because, although they can touch on the same subject matter, they involve different areas of expertise. As Justice Kennedy elaborated (134 S. Ct. at 2238-39):

> Enforcement of the FDCA and the detailed prescriptions of its implementing regulations is largely committed to the FDA. The FDA, however, does not have the same perspective or expertise in assessing market dynamics that day-to-day competitors possess. Competitors who manufacture or distribute products have detailed knowledge regarding how consumers rely upon certain sales and marketing strategies. Their awareness of unfair competition practices may be far more immediate and accurate than that of agency rulemakers and regulators. Lanham Act suits draw upon this market expertise by empowering private parties to sue competitors to protect their interests on a case-by-case basis. By 'serv[ing] a distinct compensatory function that may motivate injured persons to come forward,' Lanham Act suits, to the extent they touch on the same subject matter as the FDCA, 'provide incentives' for manufacturers to behave well. Allowing Lanham Act suits takes advantage of synergies among multiple methods of regulation. This is quite consistent with the congressional design to enact two different statutes, each with its own mechanisms to enhance the protection of competitors and consumers (citations omitted).

Finally, the Supreme Court explained why it rejected the Government's position that a Lanham Act suit is precluded "to the extent the FDCA or FDA regulations **specifically require or authorize** the challenged aspects of [the] label." *Id*. at 2240. The Supreme Court reasoned that "[i]n addition to raising practical concerns about drawing a distinction between regulations that 'specifically authorize' a course of conduct and those that merely tolerate that course, . . . the flaw in the Government's intermediate position is . . . [that] the Government assumes that the FDCA and its regulations are at least in some circumstances a ceiling on the regulation of food and beverage labeling." *Id*. at 2240, *quoting* Amicus Br. 10-11. According to the Supreme Court, the error in the Government's assumption is that nothing in the language of the FDCA or FDA's juice-naming regulation suggests that FDA regulation represents a ceiling above which a Lanham Act court cannot go, particularly because FDA's "rulemaking does not discuss or even

cite the Lanham Act, and the Government **cites no other statement . . . suggesting that the FDA considered the full scope of the interests the Lanham Act protects**." *Id*. at 2241.

Contrary to SPD's position, this aspect of the Supreme Court's analysis applies, if anything, with even more force to FDA's Class II device regulation scheme. That is because, unlike with medical devices, juice drinks do not contain package inserts. *See generally* 21 CFR § 102.33. In other words, whereas FDA-authorized or required juice label language appears where consumers can see it before they purchase the product, that is not the case with home pregnancy tests or other medical devices, as this Court recognized. And as this Court also recognized, an effect of FDA-approved or required disclosures that appear in a product insert is that while they conceivably may satisfy FDA's concerns about providing necessary health and safety information before a consumer **uses** a pregnancy test, they would not satisfy the Lanham Act's concerns about protecting a pregnancy test manufacturer's competitors from false advertising that deceives consumers **at or before the point of product purchase**, and thereby injures those competitors by diverting sales to the false advertiser. MTD Op. 24-25 & n.6.[7]

III. *POM WONDERFUL* APPLIES TO LANHAM ACT CASES CHALLENGING LABELING AND OTHER ADVERTISING OF HOME PREGNANCY TESTS

SPD is hardly in a position to argue that *POM Wonderful* does not apply to medical devices, since its motion to dismiss on grounds of FDCA preclusion relied heavily on the Ninth Circuit's *POM Wonderful* decision. *See* Dkt. 59 at 10-11, 13, 15. Obviously, the relevance of

[7] SPD's contrary position regarding the reach of *POM Wonderful* is set forth in such cursory fashion it is hard to follow. *See* SPD Br. 18, *citing* 134 S. Ct. at 2239. SPD seems to contend that the Supreme Court's passing mention of the fact that unlike drug labels, food and beverage labels are not pre-approved shows that the Court viewed its ruling as inapplicable to Lanham Act cases involving drugs and Class II medical devices (which devices the Supreme Court's opinion does not even mention). Such an argument not only is completely at odds with the Supreme Court's extensive, multi-layered analysis of the Lanham Act's and FDCA's statutory language and differing purposes, it is also at odds with the FDA's explicit recognition in its Weeks Estimator Clearance Letter that FDA's clearance was **not** a finding that the Product or its labeling complied with the FDCA or any other federal statutes. *See* MTD Op. 8.

POM Wonderful to this case cannot turn on whether or not the outcome at a particular stage in that case favors SPD. Moreover, as shown in Point II, the Supreme Court's rationale for its decision applies at least with equal force to medical devices. The only two known cases to have considered this issue – *JHP Pharms., LLC v. Hospira, Inc.*, 2014 U.S. Dist. LEXIS 142797 (C.D. Cal., Oct. 7, 2014), and *Catheter Connections, Inc. v. Ivera Med. Corp*., 2014 U.S. Dist. LEXIS 98206 (D. Utah July 17, 2014) – support C&D's position.

SPD characterizes *JHP* and *Catheter Connections* as holding that *POM Wonderful* "**did not do away with the doctrine of FDCA preclusion**." SPD Br. 19. But C&D does not claim otherwise: it has never argued, either in this litigation or the previous one with SPD, that a Lanham Act suit alleging false advertising of an FDA-regulated product can never be precluded under any circumstances. To the contrary, C&D's briefs submitted last year in connection with SPD's motion to dismiss noted a few factual scenarios **not present in this case** as to which preclusion arguably might still apply even after the Supreme Court decided *POM Wonderful*. *See, e.g.*, C&D Preliminary Injunction Reply Memorandum at 10 n.8 (Dkt 78); C&D Memorandum in Opposition to Dismiss at 17 (Dkt 71).

In *JHP Pharms*., the issue was whether defendants that sold a drug without FDA approval could be liable under the Lanham Act for certain statements and omissions made about that drug. After discussing the Supreme Court's decision, the *JHP* Court rejected defendants' argument that *POM Wonderful* was only limited to food and beverage labels, and concluded that despite the Supreme Court's "frequent mention" of food and beverage labeling and its suggestions of some "difference[s] between food and drug labeling" (*id*. *11-12), the "arguments, logic and holding of *POM Wonderful* are couched in much broader language and strongly suggest a more wide-ranging application." *Id*. *12. The *JHP* court thus concluded that

the "logical building block of the [Supreme] Court's specific holding with regard to food and beverage labeling would seem to be equally applicable to food and beverage advertising, drug marketing [or] **medical device labeling** . . . ." except where the court is called upon "to make determinations within the **exclusive** purview of FDA authority . . . ." *Id*. *12-13, 25.

Here, it is not within FDA's expertise or purview – exclusive or otherwise – to consider the interests of SPD's competitors. It is within FDA's purview to focus on whether, by the time a consumer uses the Weeks Estimator, there is sufficient information available to her, including in the package insert that she will not read (if at all) until **after** she purchases the Product and opens the package, to minimize product misuse. But as this Court recognized (MTD Opp. 24 n.6), that is a different focus than the Lanham Act's focus, which assesses whether competitors are likely to lose sales because of deceptive statements on the Weeks Estimator's outside package label that consumers see and are influenced by prior to purchase. In short, under the arguments, logic and holding of *POM Wonderful*, none of the SPD advertisements challenged by C&D under the Lanham Act is precluded by the FDCA.

Catheter Connections, which was decided shortly after the Supreme Court decision, is to the same effect as *JHP*. There the District Court also found the analysis of *POM Wonderful* applicable to Lanham Act false advertising cases involving FDA-regulated medical devices. *See id*. *18-19 ("it is clear from POM Wonderful that claims based upon false statements about the nature of a regulated [medical device] product are not barred by the FDCA"). The Court then held that none of plaintiff's Lanham Act claims was precluded, save one which turned on whether a revised version of a previously-cleared product required a new 510(k) clearance, a matter the Court held was "within the FDA's exclusive jurisdiction." *Id*. *15-16.

IV. THE CONFLICT SPD ALLEGES DOES NOT EXIST

Even if the Court were to side with SPD that the "actual conflict" line of cases survived *POM Wonderful*, it still should deny SPD's motion. First, the conflict SPD alleges is illusory. Second, in all events the issue is premature; whether a conflict might exist turns on the precise nature of the injunctive relief this Court may provide, but that will not be considered until the liability issues have been adjudicated, at which point the Court would have a full record on which to consider appropriate injunctive relief.

First of all, there is no basis to claim a conflict will result. According to SPD, FDA prohibited it from placing a "Conversion Chart" on the outside of the Weeks Estimator package. SPD Br. 15-16, 21 n.9.[8] But even if that were true (and it is not), the Complaint does not ask the Court to force SPD to put a "Conversion Chart" on its outside package. Thus, no matter what FDA actually said about SPD's placement of the Conversion Chart, it does not conflict with C&D's Lanham Act claims. To state the point simply, C&D asks this Court to find that the Original and Revised Package labels (as well as the other challenged advertising) are false and misleading, and to enjoin SPD from further use of that advertising and any other advertising that conveys the same false messages. It does not propose (at least at this time) that the injunction instruct SPD on how not to violate the Lanham Act in future labeling or other advertising. Thus, what use SPD might make of the Conversion Chart in the future is not part of the relief C&D now seeks, and thus no "conflict" exists between that relief and what SPD falsely claims FDA would not allow it to do.

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[8] The Conversion Chart is in the bottom right corner of the package design SPD submitted to FDA in August 2012 (Ex. 30). The Conversion Chart (like a similar chart featured in the package insert today) explains, for any given Weeks Estimator result, how a doctor would **differently** date the user's pregnancy in terms of weeks since LMP and describes the doctor's different measure as "**weeks pregnant**." In contrast, the Product's result is described as "weeks since ovulation."

In any case, it is clear FDA **did not** direct SPD to remove the Conversion Chart from the outside package label. SPD says FDA's September 2012 Hold Letter required it to do so, pointing to a paragraph in the letter directing it to remove from the outside label a "statement describing the minimum accuracy of the weeks estimation indicator." Ex. 1 at 6. But FDA was not referring to the Conversion Chart, but rather to a **different** statement on the box that said "The accuracy of the Weeks Indicator is 76% or greater . . . ." *See* Ex. 30. This is clear from the fact that SPD itself previously used the phrase "**statement describing the minimum accuracy**" to refer to the "76% accurate or greater" statement, not the Conversion Chart. [redacted]. Thus,

when FDA later sent the Hold Letter, it simply adopted SPD's terminology to refer to the "76% accurate or greater" statement.[9]

Likewise, SPD's suggestion that FDA mandated a broader, nebulous prohibition against displaying "Performance of the Weeks Estimator" also fails. First, C&D is not demanding that "Performance of the Weeks Estimator" be displayed on the box labeling; rather, it is asking this Court to direct that SPD's advertising convey clearly to consumers that the Product does not estimate how long a woman has been pregnant. Second, nothing in FDA's correspondence suggests that it prohibited SPD from conveying that message.[10]

Taken to its logical end, SPD's argument would allow for this scenario: Assume SPD anticipated C&D would bring a Lanham Act suit because SPD planned to advertise the Product in a way to mislead consumers into believing it estimated the length of pregnancy the same way a doctor does. SPD then proposed language to FDA it knew FDA would reject as too vague, such as: "Both this test and doctors measure how long you are pregnant, but our test is somewhat different." Now suppose the FDA examiner responded (of course, without consulting C&D): "please remove that entire discussion from the outside of the box and place it in the insert, where you can provide more detailed information." According to SPD's theory, it would then be free to argue it is immune from Lanham Act liability for an advertising claim falsely communicating that the Product estimates the duration of pregnancy the same way a doctor does because "we offered to put something similar to that on the outside of the box and FDA said 'no'."

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[9] FDA used markedly different language to describe a version of the Conversion Chart in the package insert, calling it "a table . . . indicating how the doctor will rate (sic) pregnancy compared to the weeks estimation results obtained from your device." *See* Ex. 1 at 7.

[10] Other FDA correspondence shows that FDA used the phrase "Performance of the Weeks Estimator" not to refer to the Conversion Chart, but rather to refer to the statement that ended up replacing the "76% accurate or greater" statement on the package insert: "Agreement of Weeks Estimator results with clinical findings ranged widely from 45-99%." *See* Ex. 11 at 6; *see also* Ex. 24 at 34:4-10.

V. SPD'S FOCUS ON THE MESSAGE CONVEYED BY THE PACKAGE INSERT IS MISPLACED AND IGNORES KEY EVIDENCE OF CONSUMER DECEPTION

SPD contends that C&D lacks evidence that consumers are misled by the fact that certain disclosures about the Weeks Estimator are located on the inside of the package (as part of the Product's package insert) instead of the outside. This argument is preposterous.

SPD's contention that the "record is ***devoid*** of evidence" of consumer deception caused by the carton's exterior (SPD Br. 17 (emphasis in original)) is not an issue to be resolved in a motion *in limine*, but rather after trial. First, C&D does not need to present ***any*** evidence of deception if the Court finds the Weeks Estimator advertising literally false, as C&D has alleged. *Time Warner Cable, Inc. v. DIRECTV, Inc.*, 497 F.3d 144, 153 (2d Cir. 2007) ("When an advertisement is shown to be literally or facially false, consumer deception is presumed").

In all events, there is ample evidence that both the Original and Revised Package mislead consumers and affect their purchasing decisions. A survey by one of C&D's experts, Hal Poret, showed that a very substantial percentage of survey participants understood the Original and Revised Package to each communicate what C&D alleges are the false messages that (i) the Weeks Estimator estimates the number of weeks a woman has been pregnant; and (ii) the number of weeks the Weeks Estimator estimates is the same number of weeks pregnant a doctor would tell her. The survey also showed that the Original and Revised Packages are likely to influence consumers' purchasing decisions. Ex. 25 ¶¶ 102-10. There is also extensive additional evidence that the false and misleading messages communicated by the Original and Revised Packages and other SPD advertisements are likely to influence consumer purchasing decisions. *See* Ex. 13 ¶¶ 57-63; Ex. 26 ¶¶ 64-79.

Second, SPD's suggestion that any deception is cured by the package insert is absurd on its face. It is not only common sense but also the law that a consumer cannot be influenced by

what she cannot see. *See, e.g.*, *Time Warner Cable, Inc. v. DIRECTV, Inc.*, 2007 U.S. Dist. LEXIS 28209, at *14 n.6 (S.D.N.Y. Apr. 16, 2007), *aff'd* 497 F.3d 144 (2d Cir. 2007). Here, a consumer [redacted] Product **purchase**. Moreover, there is strong evidence women will not read the package insert even after purchase. [redacted][11]

VI. C&D DOES NOT SEEK TO ATTACK FDA'S CLEARANCE OF THE PRODUCT FOR ITS INTENDED USE OF ESTIMATING THE NUMBER OF WEEKS SINCE OVULATION

SPD contends that "discovery has revealed" that C&D is not seeking the relief specified in its Complaint, but actually seeks to block SPD's ability to sell the Product in the U.S. by undoing FDA's clearance. SPD Br. 1. That is patently false. Nowhere does the Complaint ask the Court to revoke FDA's clearance or request an injunction on the sale of the Product altogether, regardless of how it is advertised, and C&D represents that it will not seek from this Court revocation of FDA's clearance of the Product as safe and effective for the intended use of estimating the number of weeks since a woman ovulated.

[11] Moreover, it is not C&D's responsibility to conduct a survey on this issue to avoid a finding of FDCA preclusion. SPD has asserted FDCA preclusion as an affirmative defense (*see* SPD's Answer [Dkt 105] at 15), so to the extent that defense depends on showing that consumers would perceive the Product differently if information on the package insert were placed on the external carton, SPD bears the burden of proof. *See Cowden v. BNSF Ry. Co.*, 690 F.3d 884, 892-93 (8th Cir. 2012) (defendant had the burden to show federal regulations applied to and substantially subsumed plaintiff's claim under the Federal Employer's Liability Act); s*ee also Bravman v. Baxter Healthcare Corp.*, 842 F. Supp. 747, 753 (S.D.N.Y. Jan. 24, 1994) (noting, in the related context of federal preemption, "the party claiming preemption . . . has the burden of proof and must establish that Congress has spoken clearly and made its intention to preempt unmistakable").

To be clear, C&D's challenge encompasses certain SPD advertisements that contain the words "weeks since ovulation." C&D is challenging these advertisements because, in context, they still convey the false message that the Product estimates "weeks pregnant" and provides the same estimate as a doctor. But C&D has not alleged the Product is incapable of being marketed truthfully in a manner that clearly conveys that the Product estimates weeks since ovulation and that the Product's estimate is different than a doctor's estimate of weeks pregnant. Thus, C&D's Complaint intentionally stops well short of seeking an order precluding sale of the Product irrespective of how it is advertised. As such, this suit does not seek to reverse FDA's clearance.

In that regard, SPD's contention (SPD Br. 23-24) that C&D's witnesses opined that the "Product would be misleading" no matter how it is marketed is inaccurate. But even if any of C&D's party or expert witnesses personally believed the Product could not be advertised or sold under any circumstances without misleading consumers and threatening their safety, C&D is simply not asking this Court to revoke FDA's clearance.

CONCLUSION

Based on the foregoing, the Court should deny in its entirety SPD's motion *in limine* to dismiss C&D's false advertising claims.

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New York, NY

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